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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,594	04/22/2004	Ken-Jen Yu	3744-043984	6879

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

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11/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,594	Applicant(s) YU, KEN-JEN	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7-9,11-13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,11-13 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 14 July 2009. Claims 1, 3, 5, 7-9, 11-13 and 15-22 are now pending. The Examiner acknowledges the amendments to claims 1, 3, 5, 7-9, 12, 13, 18, 20 and 22, as well as the cancellation of claims 10 and 14 and the addition of claim 22.

Election/Restrictions

2. Newly submitted claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: because new claim 22 is directed towards disposing a skin graft into a vagina, whereas the original invention is directed towards a vaginal mold.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 9, 11-13 and 15-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 recite(s) the

“plural petal structures being disposed in a reconstructed vagina” and claim 13 recites that the “plural petal porous structures are disposed in a vagina”. Claim 12 recites “said reconstructed vagina has an opening end and said opening end is nearby said opening.” This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 5, 7, 8 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 at line 4 recites “a porous main body having a hollow columnar structure and a first jointing structure, supporting said reconstructed vagina and being independently removable from said reconstructed vagina...” It is unclear, based on this recitation, which structure is supporting the vagina and which structure is independently removable from the reconstructed vagina.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 5, 7, 9, 11-13, 15-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cattanach (U.S. Patent No. 5,013,297). Cattanach discloses an apparatus comprising a hollow longitudinally extending member for placement within the vagina. Regarding claims 1, 3, 7, 9, 11 and 13, Cattanach teaches a device comprising a porous main body having a hollow columnar structure **2**, a porous minor part **3** and a "jointing structure" (screwthread or fastener) of said main body and said minor part for connection between the two (Figs. 1 and 2 and col. 4, lines 40-52). The main and minor parts are also interpreted as the "plural petal structures" in accordance with claim 9 because there is no special technical definition associated with this particular structure in the specification, hence, the broadest reasonable interpretation of the term "petal" is given. Many different shapes and types of petals exist, therefore a possibility of many different interpretations also exist. Regarding claims 18 and 19, the petal structures are porous due to openings **11**, and flow passage **5** (Figs. 1 and 2). Further regarding claim 19, the openings are capable of passing a tissue fluid therethrough. Regarding claim 5, the porous minor part has an arc-shaped surface (Fig. 2).

With respect to claim 12, the device is considered to be a "one-end opened hollow structure" with an open end (both parts have an "open end" which allows connection between the two) as depicted in Fig. 2. Regarding claims 15-17, the plural structures are identical structures (Fig. 5), yet are also different as evidenced by Fig. 1.

Regarding claim 21, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the device of Cattnach is inserted into the vagina, it is capable of being used for vaginal reconstruction.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cattnach (U.S. Patent No. 5,013,297) in view of Abbott et al. (U.S. Patent No. 7,276,056) and further in view of Gehling (U.S. Pub. No. 2003/0144639). Cattnach discloses the invention as claimed, see rejection supra; however Cattnach fails to disclose that the vaginal device is covered by a skin graft. Abbott et al. (hereinafter Abbott) discloses a douching device for applying a therapeutic substance to a patient. Regarding claim 20, Abbott teaches that the douching device may also be used to introduce or apply one or more therapeutic substances into the vaginal canal (col. 18, lines 66-67 - col. 19, lines 1-18). However, the combination of Cattnach and Abbott fails to disclose that the therapeutic substance is a skin graft. Gehling discloses a tampon adapted to deliver a therapeutic agent to a patient. Regarding claim 20, Gehling teaches the application of various vaginal therapeutic materials [0002] such as

grafting material [0024]. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated a grafting material for therapeutic treatment as suggested by Gehling, to a device for applying a therapeutic substance as suggested by the combination of Cattnach and Abbott, in order to promote healing and tissue growth within a human cavity.

Allowable Subject Matter

11. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 8, while the prior art of record teaches a vaginal mold detachable in a reconstructed vagina via a screw structure, the prior art of record fails to teach or suggest a vaginal mold detachable in a reconstructed vagina as claimed by Applicant, wherein the mold further comprises a support that holds the porous minor part when the porous main body is detached from the minor part and removed from the vagina.

Response to Arguments

12. Applicant's arguments filed 14 July 2009 with respect to the rejection of claims 1, 3, 5, 7 and 18-21 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive, however a new grounds of rejection is presented above in view of the new amendments to the claims.

13. Applicant's arguments filed 14 July 2009 with respect to the rejection of claims 1, 3, 5, 7-19 and 21 under 35 U.S.C. 102(b) citing Cattanach ('297) have been fully considered and are not persuasive. Applicant contends that the minor part **3** of Cattanach is not porous and it would be impossible to have a porous structure since the minor part **3** is a douching solution container. However, this argument is not persuasive. As noted in the previous Office action and also the rejection above, openings **11** and a flow passage **5** (passage which allows movement of solution from the minor part **3** to the main body **2**) constitute the "porous" main and minor parts, respectively.

Applicant further contends that it is impossible for the main body **2** and the minor part **3** to be detachable in the vagina. However, this argument is not persuasive. The screwthread or snap-lock arrangement (col. 4, lines 40-52) between the main body and minor part allow the two components to be detachable in the vagina.

14. Applicant's arguments filed 14 July 2009 with respect to the rejection of claim 20 under 35 U.S.C. 103(a) citing Cattanach ('297) in view of Abbott ('056) and further in view of Gehling ('639) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with respect to claim 1, which were not found persuasive for the reasons addressed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D. H./
Christine D Hopkins
Examiner
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